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January 30, 2006

The Honorable Kent A. Jordan
United States District Judge
844 North King Street, Room 6325
Wilmington, Delaware 19801

VIA ELECTRONIC FILING

Re: In re '318 Patent Infringement Litigation, Civil Action No.
05-356-KAJ (consolidated)

Dear Judge Jordan:

Pursuant to ¶ 4(f) of the Court's Scheduling Order and Rule 37 of the Federal Rules of Civil Procedure, Plaintiffs submit this letter seeking the Court's assistance in a discovery dispute. Specifically, Plaintiffs seek an order by the Court compelling defendant Mylan Corp. ("Mylan") to produce discovery related to patent validity as well as to willfulness that Mylan has refused and/or failed to produce. Mylan's continuing failure to produce the documents is not supported by any legitimate reason and has hampered Plaintiffs' development of their case – particularly in view of the accelerated schedule adopted at defendants' insistence.

On September 12, 2005, Plaintiffs served their First Set of Requests for Documents and Things on all defendants, including Mylan. These requests sought the production of certain documents related to patent validity and to Plaintiffs' allegations of willful infringement, including:

- Request No. 3(d): "... documents relating to the decision to file [the ANDA]";
- Request No. 16: "All documents relating to [defendants'] Notice of Paragraph IV Certification to [plaintiffs]";
- Request No. 17: "All documents relating to the analysis or evaluation for any purpose of any drug product containing galantamine or any salt thereof, including but not limited to Janssen's RAZADYNE®/REMINYL®" products;
- Request No. 20: "All documents relating to the '318 patent, including without limitation (a) any evaluation, analysis, or discussion relating to the '318 patent; (b) communications between [defendants] and any third party concerning the '318 patent"; and

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- Request Nos. 4 and 10: “All documents relating to the research and development of any galantamine product” or “any product intended to treat dementia of the Alzheimer’s type.”

See Pls.’ First Set of Requests for Documents and Things, *Janssen Pharmaceutica N.V. v. Mylan Pharm. Inc.*, C.A. No. 05-371 (Ex. A).¹

To date, Mylan has produced only a copy of the ’318 patent, its file history, four prior art references, Mylan’s ANDA 77-590, and a copy of the complaint against Mylan in this action.² Further, Mylan’s Objections and Responses to Plaintiffs’ First Requests contain the boilerplate response that it will “produce all responsive, non-privileged documents relevant to the issues of infringement. . . and the validity of the ’318 patent.” See Mylan’s Objections (Ex. B). This evasive response is unacceptable: Mylan must produce all responsive documents, and not merely those that it unilaterally decides are relevant to infringement and validity. Indeed, this response leaves Plaintiffs to guess what documents Mylan has decided to secretly withhold on the basis of its qualification.³

Under Rule 26 of the Federal Rules of Civil Procedure, parties are entitled to obtain any non-privileged discovery that is “relevant to the claim or defense of any party.” Fed. R. Civ. P. 26(b). Discovery is “relevant” if it appears “reasonably calculated to lead to the discovery of admissible evidence.” *Id.* Rule 37 authorizes the Court to compel material that is discoverable under this standard. Fed. R. Civ. P. 37.

The particular document requests at issue seek information relevant to objective considerations of non-obviousness, such as long-felt need, failure of others, skepticism in the relevant art, commercial success, commercial acquiescence (licensing), professional approval, and copying. See, e.g., *United States v. Adams*, 383 U.S. 39, 51 (1966) (skepticism of those skilled in the art); *Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH*, 139 F.3d 877, 885 (Fed. Cir. 1998) (same); *Minnesota Mining & Mfg. Co. v. Johnson & Johnson Orthopedics, Inc.*, 976 F.2d 1559, 1574 (Fed. Cir. 1992) (failure of others and commercial acquiescence); *Jenn-Air Corp. v. Modern Maid Co.*, 499 F.Supp. 320, 326-27 (D. Del. 1980) (professional approval); *Dow Chem. Co. v. American Cyanamid Co.*, 816 F.2d 617, 622 (Fed. Cir. 1987) (copying). Such objective evidence may be the “most probative and cogent evidence” of nonobviousness of the patent, *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1537 (Fed. Cir. 1983), and it “must always” be considered by the Court, *Fromson v. Advance Offset Plate, Inc.*, 755 F.2d 1549, 1556 (Fed. Cir. 1985). To the extent defendants themselves (including Mylan) expressed such skepticism before their recent assertions that the ’318 patent was

¹ Plaintiffs propounded similar but not identical document requests on all defendants.

² The other defendants in this action have fared no better, having produced few (and, in some cases, no) responsive documents.

³ Plaintiffs have tried to resolve this dispute informally. In the most recent exchange of correspondence (see 1/23/06 Calia letter to Siwik and 1/25/06 Brody letter to Calia, Exs. C and D), Mylan responded to Plaintiffs’ concerns about these documents by either denying that a dispute exists or by diverting attention to alleged discovery deficiencies of Plaintiffs.

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“obvious,” that evidence would be even more highly probative. *See Amstar Corp. v. Envirotech Corp.*, 730 F.2d 1476, 1478-79 (Fed. Cir. 1984).

Two disputed requests (Request Nos. 3.d. and 16) seek documents concerning the ANDA filings that led to the present litigation, and it is therefore difficult to imagine a more relevant subject for discovery. Other disputed requests (Request Nos. 4, 10, 17, and 20) concern the evaluation, analysis, or research and development of galantamine-containing products or products used to treat Alzheimer’s disease. Such documents are clearly reasonably calculated to lead to the discovery of admissible evidence on at least the objective considerations of long-felt need, failure of others, and skepticism in the art.

The materials sought by Plaintiffs are also discoverable under Rule 26(b) because Plaintiffs have alleged that Mylan has willfully infringed the ’318 patent. *See* Compl. ¶ 34, *Janssen Pharamceutica N.V. v. Mylan*, C.A. No. 05-371. Before a party files an ANDA and Paragraph IV certification or engages in any other potentially infringing conduct, that party must satisfy a duty of care to determine whether or not the conduct would infringe the patent holder’s rights. *Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.*, 383 F.3d 1337, 1343 (Fed. Cir. 2004). If the party’s decision to engage in the conduct in light of that duty was not reasonable, then the infringement was willful. *Am. Med. Sys., Inc. v. Med. Eng’g Corp.*, 6 F.3d 1523, 1530 (Fed. Cir. 1993).⁴

Mylan’s motion to dismiss Plaintiffs’ willfulness allegations or in the alternative for bifurcation and stay of discovery on willfulness does not affect Plaintiffs’ entitlement to this discovery: as shown above the requested materials also bear on patent validity issues, which Mylan has placed at issue by asserting defenses and counterclaims of invalidity. Infringement and willful infringement alike depend on the merit of Mylan’s invalidity defense – willful infringement merely requires further analysis as to whether that defense was asserted unreasonably. *See, e.g., Kaufman Co. v. Lantech, Inc.*, 807 F.2d 970, 979 (Fed. Cir. 1986) (upholding willfulness determination based on assertion of frivolous patent infringement defense).

Mylan has had ample opportunity since receiving the document requests on September 12, 2005 to produce documents responsive to the disputed requests and has failed to do so. Plaintiffs therefore ask this Court to order Mylan to produce these relevant documents immediately. We hope to speak with Your Honor by telephone on either the February 1, 6, or 7 dates offered by the Court. So far, Mylan has rejected all three dates, but its rejection of the earliest date was based on the assumption that the deadlines for submitting letters in advance of that time no longer could be met. We are submitting this letter by the 48-hour opening letter deadline, in the hope that Mylan now will agree to proceed on that date so that this matter can be heard without further delay.

⁴ Also, Mylan may rely on an advice-of-counsel defense, in which case Mylan would be deemed to have waived privilege and the opinions of counsel would be discoverable as well. *Winbond Elec. Corp. v. Int’l Trade Comm’n*, 262 F.3d 1363, 1375 (Fed. Cir. 2001). Plaintiffs’ discovery requests seek to elicit such relevant information and are therefore well within the scope of materials that can be compelled under Rule 37.

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Respectfully,

/s/ Steven J. Balick

Steven J. Balick

SJB/dmf
Attachments
166181.1

cc: George F. Pappas, Esquire (via electronic mail; w/attachments)
Josy W. Ingersoll, Esquire (via electronic mail; w/attachments)
Edward C. Donovan, Esquire (via electronic mail; w/attachments)
Mary B. Matterer, Esquire (via electronic mail; w/attachments)
William A. Rakoczy, Esquire (via electronic mail; w/attachments)
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